UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
SAN ANTONIO DIVISION

MARIA RAMIREZ, *Plaintiff*	§ §	
v.	§ §	Case No. SA-23-CV-01419-XR
SANOFI U.S. SERVICES, INC., SANOFI-AVENTIS U.S. LLC, *Defendant*	§ §	

JOINT FED. R. CIV. P. 26 REPORT

1. **Are there any outstanding jurisdictional issues? For removed cases based on diversity jurisdiction, do the parties agree that the amount in controversy exceeded $75,000 at the time of removal? If not, each party should state its position on the amount in controversy.**

   There are no outstanding jurisdictional issues.

2. **Are there any unserved parties? If more than 90 days have passed since the filing of the Complaint or petition, should these unserved parties be dismissed?**

   There are no unserved parties.

3. **What are the causes of action, defenses, and counterclaims in this case? What are the elements of the cause(s) of action, defenses, and counterclaims pled?**

This products-liability case was, until recently, one of more than 10,000 pending in the Eastern District of Louisiana as part of *In re: Taxotere (Docetaxel) Products Liability Litigation*, MDL 2740. The suit arises out of Plaintiff's use of, and alleged injury from, Taxotere, a chemotherapy drug manufactured by Defendants Sanofi U.S. Services Inc. and sanofi-aventis U.S. L.L.C. ("Sanofi"). Although Plaintiff asserts a variety of claims, the gravamen of the action relates to Sanofi's alleged failure to adequately warn Plaintiff that Taxotere can cause permanent hair loss.

Plaintiff alleges that she was prescribed Taxotere to treat her breast cancer from October 13, 2009, to February 1, 2010, and that as a result of this treatment she suffered permanent hair loss. She alleges that Sanofi was aware that Taxotere had the potential to cause permanent hair loss but failed to adequately warn her or the healthcare providers who prescribed and administered the drug. Plaintiff filed her action on October 23, 2017.

Sanofi disputes Plaintiff's claims. Sanofi contends that the Taxotere label was approved by the FDA and has always contained accurate, science-based information enabling doctors to make informed decisions about the benefits and risks of prescribing Taxotere within its approved indication. Sanofi also contends that Plaintiff's claims are barred by the statute of limitations, as she filed this action six years after completing her chemotherapy regimen.

Key legal issues remaining in this case include:

- whether Plaintiff's claims are barred by the statute of limitations;
- whether Plaintiff's claims are barred by the "learned intermediary doctrine";
- whether Taxotere causes permanent hair loss (general causation);
- whether Taxotere caused Plaintiff's injury (specific causation);
- whether the warning on Taxotere's labeling was sufficient given the risks;
- whether Plaintiff would still have taken Taxotere even with a warning that fully disclosed the risk of permanent hair loss; and
- the amount of damages due, if any.

4. Are there any agreements or stipulations that can be made about any facts in this case or any element in the cause(s) of action?

None at this time.

5. State the parties' views and proposals on all items identified in Fed. R. Civ. P. 26(f)(3).

On October 4, 2016, pursuant to 28 U.S.C. § 1407, the Judicial Panel on Multidistrict Litigation ("JPML") created *In re: Taxotere (Docetaxel) Products Liability Litigation,* MDL 2740, in the United States District Court, Eastern District of Louisiana, to coordinate pretrial discovery

among thousands of individually filed product liability actions against manufacturers of the chemotherapy drug docetaxel, including Sanofi, which manufactures the drug under the brand-name Taxotere. The MDL is pending before the Honorable Jane Triche Milazzo. Since that time, more than 15,000 lawsuits have been filed in the MDL against a number of defendants, and more than 10,000 cases are currently still pending in that Court, including approximately 6,000 naming only Sanofi.

On May 12, 2023, the MDL Court found that the "purposes behind consolidation [had] been served," and transferred 81 "Wave 1" cases to "the appropriate district courts" in accordance with 28 U.S.C. § 1404. *See In re Taxotere (Docetaxel) Prod. Liab. Litig.*, No. 2:16-md-02740, Doc. 15836, at 1–2 (E.D. La. May 12, 2023). More recently, the MDL Court has started another wave of remands, resulting in the transfer of 25 cases to district courts in Texas, including this case. Although a substantial number of these cases have since settled, many remain pending.

The parties have agreed to waive initial disclosures. The parties in the MDL stipulated to forgo Rule 26(a)(1) initial disclosures, and general, company-liability discovery has already been completed as part of the MDL proceeding. Given the lengthy litigation history in this case, both parties are well aware of the available sources of evidence.

The parties agree that production of electronically stored information should comply with the terms of the MDL Court's ESI Protocol, *see In re Taxotere (Docetaxel) Prod. Liab. Litig.*, No. 2:16-md-02740, Pre-trial Order No. 49, Ex. 1 (E.D. La. July 6, 2017), and Pretrial Order Governing Plaintiffs' Responsibilities Relevant to ESI, *see In re Taxotere (Docetaxel) Prod. Liab. Litig.*, No. 2:16-md-02740, Pre-trial Order No. 71A, Ex. 2 (E.D. La. Jan. 26, 2018).

In the MDL, the Court entered PTO 71 to govern Plaintiff's identification, preservation, collection and production of ESI. *Id.* at 10. PTO 71 outlined the relevant, potential sources of ESI

Plaintiffs should search for responsive information; mandated reasonably diligent searches of the ESI Sources; identified search terms each Plaintiff or her attorney would run through available search functions in the ESI Sources; and required each Plaintiff to submit a written disclosure statement to Defendants to be produced with responsive documents. *Id.* In January of 2018, PTO 71 was amended and superseded by PTO 71A, which was identical in substance to PTO 71 but provided Plaintiffs additional time to comply with its requirements. *Id.*

The parties agree that trial-preparation materials should be protected in accordance with the MDL Court's ESI Protocol, *see In re Taxotere (Docetaxel) Prod. Liab. Litig.*, No. 2:16-md-02740, Pre-trial Order No. 49, Ex. 1 (E.D. La. July 6, 2017), and Protective Order, *see In re Taxotere (Docetaxel) Prod. Liab. Litig*., No. 2:16-md-02740, Pre-trial Order No. 50, Ex. 3 (E.D. La. July 6, 2017).

The parties request that the Court set a scheduling order that reflects the fact that this case is one of hundreds being remanded across the country. In light of the burdens represented by these cases, particularly as it pertains to discovery, the parties request that the Court set the case for trial in May 2025.

Sanofi will likely bring a motion for judgment on the pleadings based on the statute of limitations. In the event judgment on the pleadings is denied, Sanofi will file an early motion for summary judgment based on the statute of limitations and the learned intermediary doctrine.

6. What, if any, discovery has been completed? What discovery remains to be done? Have the parties considered conducting discovery in phases?

To date, minimal case-specific discovery has been conducted in this case. Specifically, limited records collection has occurred. The exchange of Plaintiff and Defendant Fact Sheets was also undertaken in the MDL. No case-specific fact depositions have been taken.

Through coordinated proceedings in the MDL, the Court has facilitated general expert,

corporate, and third-party discovery. *See* Transfer Order, at 116–17 ("Because all general fact and expert discovery has been completed in the MDL, the courts receiving these cases need not be concerned with facilitating general expert, corporate, and third-party discovery."). General MDL discovery directed at Sanofi—which resulted in the production of 43 corporate custodial files comprising more than 500,000 documents (6.3 million pages), the deposition of 28 witnesses (including nine 30(b)(6) depositions)—concluded on December 15, 2018. *See* Transfer Order, at 79–81. The MDL Court further acknowledged it "denied additional discovery requests since that time. *Id.*

Sanofi's position is that although this body of general discovery remains available to plaintiffs for use in cases remanded from MDL 2740, no additional general discovery against Sanofi shall be permitted post- remand. *Id.* Extensive general discovery against Sanofi, including punitive damages discovery, was conducted for the benefit of all cases pending in the MDL, regardless of venue pursuant to the General Discovery Order entered in the MDL. Consistent with the purposes of an MDL, general and punitive damages discovery was not limited to issues relevant to Louisiana law. See Ann. Manual Complex Lit. § 22.8 (4th ed.) (MDL courts typically "direct initial discovery toward matters bearing on the defendants' liability to all plaintiffs"). Under the General Discovery Order, the MDL court limited Plaintiffs to 30 depositions of Sanofi witnesses, including current and former employees and corporate representatives. The deadline for general discovery against Sanofi expired on December 15, 2018. Since that time, the MDL court has denied additional general discovery requests against Sanofi. Plaintiff's position is that general discovery was not taken on the issue of punitive damages, as defendants took the position that such discovery was case/state specific and because *Lexecon* prevented the trial of a case in a jurisdiction that allowed for imposition of punitive damages. The only MDL trials were in Louisiana, where punitive

damages are not allowed in this type of case.

Before this case will be ready for trial, the parties will need to complete extensive case-specific discovery, including records collection; Sanofi may conduct written discovery (which was deferred by the MDL court until remand); multiple fact witness will be deposed; multiple treating doctors will be deposed; and the parties will need to conduct general and case-specific expert discovery. *See* Transfer Order, at 116–17 (noting that case-specific discovery and dispositive, *Daubert*, and pre-trial motions are to be anticipated on remand).

Sanofi believes that discovery should unfold in stages. Stage 1 would be limited to the issues underpinning Sanofi's anticipated early Motions for Summary Judgment (i.e., motions specific to the statute of limitations and the learned intermediary doctrine). This would likely be limited to deposition of Plaintiff and her prescribing physician. Stage 2 would relate to all remaining issues, and Sanofi reserves the right to file dispositive motions on issues *other than* statute of limitations and the learned intermediary doctrine during Stage 2. Sanofi believes staged discovery is appropriate because the parties will need relatively little discovery in order to fully brief the issues Sanofi intends to raise on early summary judgment. In the event the motion is successful—dozens of motions raising these issues have been granted over the course of this litigation—it would spare the parties the considerable expenses associated with discovery of the remaining issues, particularly expert discovery.

7. What, if any, discovery disputes exist?

Other than the parties' respective positions on the items identified in Federal Rule of Civil Procedure 26(f)(3) in response to item 5, above, none at this time.

8. **Have the parties discussed the desirability of filing a proposed order pursuant to Federal Rule of Evidence 502?**

The parties agree that no such order is necessary at this time.

9. **Have the parties discussed mediation?**

The parties are engaged in ongoing mediation through an MDL court-appointed mediator and believe this is the best method to continue settlement efforts.

Dated: December 15, 2023

s/Russell W. Lewis
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